

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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Jesse McDowell,		:
		:
Plaintiff,		:
		:
v.		:
		:
Eli Lilly and Company,		:
		:
Defendant.		:
-----		X

13 Civ. 03786 (RWS, GWG)  
ECF CASE  
ANSWER

Defendant Eli Lilly and Company (“Lilly”), by and through its undersigned attorney,  
hereby files its Answer and Affirmative Defenses to Plaintiff’s Complaint.

**PARTIES, JURISDICTION AND VENUE**

1. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 1 and therefore denies the same.

2. Lilly admits that it is an Indiana corporation with its principal place of business in Indianapolis, Indiana. Lilly also admits that it is engaged in the business of research, development, testing, manufacturing, producing, promoting, distributing, marketing, and selling prescription medications, including but not limited to Cymbalta®. Lilly denies the remaining allegations in Paragraph 2.

3. Lilly admits that it is authorized to conduct business and does conduct business in New York. Lilly denies the remaining allegations on the basis that they purport to allege conclusions of law and thus do not require a response.

4. Paragraph 4 of the Complaint purports to allege conclusions of law and thus does not require a response and on that basis Lilly denies the allegations.

5. Lilly admits that this Court has subject matter jurisdiction in the form of diversity jurisdiction.

6. Paragraph 6 purports to allege conclusions of law and thus does not require a response and on that basis Lilly denies the allegations.

### **FACTUAL ALLEGATIONS**

7. Paragraph 7 is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations.

8. Lilly admits that it researched, tested, developed, manufactured, labeled, marketed and sold Prozac®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly admits that Prozac® is in the class of prescription medications known as selective serotonin reuptake inhibitors (“SSRIs”), but denies the relevance of the information. Lilly admits that the United States Food and Drug Administration (“FDA”) approved Prozac® in 1987 as a safe and effective medication for the treatment of Major Depressive Disorder (“MDD”). Lilly admits that Prozac®’s patent expired in August 2001. Allegations pertaining to SSRIs as a class of antidepressants are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 8.

9. Lilly admits that Cymbalta® is a serotonin norepinephrine reuptake inhibitor (“SNRI”). Allegations pertaining to statements made about SNRIs are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 9.

10. Lilly denies the allegations in Paragraph 10.

11. Lilly admits that the FDA approved Cymbalta® in 2004 for the treatment of Major Depressive Disorder (“MDD”). Lilly further admits that the FDA approved Cymbalta® for the treatment of Generalized Anxiety Disorder (“GAD”) in 2007 and fibromyalgia in 2008. Lilly denies the remaining factual allegations in paragraph 11.

12. Lilly admits that the FDA approved Cymbalta® in 2004. Lilly also admits that it researched, tested, developed, manufactured, labeled, marketed, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly further admits that it promoted Cymbalta® to prescribers through its sales representatives. The allegations pertaining to the promotion of Cymbalta® utilizing Lilly sales representatives are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 12.

13. Lilly denies the allegations in Paragraph 13.

14. Lilly admits that the Cymbalta® label has included a warning on discontinuation symptoms since Cymbalta® was approved by the FDA in 2004. Lilly admits that the Cymbalta® label contains the following “WARNINGS AND PRECAUTIONS” section regarding “Discontinuation of Treatment with Cymbalta®”:

Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at 1% or greater and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, headache, nausea, diarrhea, paresthesia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue. During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these

drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta®. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate . . . .

Paragraph 14 is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations.

15. Lilly denies the allegations in Paragraph 15.

16. The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refers in Paragraph 16 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 16.

17. Paragraph 17 is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 17.

18. Lilly denies the allegations in Paragraph 18.

19. Lilly denies the allegations in Paragraph 19.

20. Lilly denies the allegations in Paragraph 20.

21. Lilly admits that the marketing campaign for Cymbalta® included the statement “Depression hurts. Cymbalta® can help.” Lilly denies the remaining characterization of Lilly’s advertising and marketing campaign, objects to the statements being taken out of context, and denies the allegations on the basis that they are vague and ambiguous as to time, content and

context. The 2008 article cited is vague and ambiguous and no title is referenced on that basis, Lilly denies the allegation. Lilly denies the remaining allegations in Paragraph 21.

22. The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refers in Paragraph 22 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 22.

23. The allegations pertaining to the sales and profitability of Cymbalta® are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 23 as characterized by Plaintiff.

24. Paragraph 24 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly further denies it had a duty to warn consumers directly of alleged risk associated with the use of Cymbalta®. Lilly denies any remaining allegations in Paragraph 24.

25. The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refers in Paragraph 25 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 25.

26. The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refers in Paragraph 26 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 26.

27. The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refers in Paragraph 27 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 27.

28. The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refers in Paragraph 28 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 28.

29. The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refers in Paragraph 29 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 29.

30. Lilly denies the allegations in Paragraph 30.

31. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 31 and therefore denies the same.

32. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 32 and therefore denies the same.

33. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 33 and therefore denies the same.

34. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 34 and therefore denies the same.

35. Lilly denies the allegations in Paragraph 35.

36. Lilly denies the allegations in Paragraph 36.

37. Lilly denies the allegations in Paragraph 37.

38. Paragraph 38 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 38 relating to Plaintiff's use of Cymbalta® and therefore denies the same.

39. Lilly denies the allegations in Paragraph 39.

40. Paragraph 40 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations relating to Plaintiff's alleged injuries and therefore denies the same.

### **COUNT I - NEGLIGENCE**

41. Lilly reincorporates and realleges its Responses to Paragraphs 1-40 of Plaintiff's Complaint as if fully set forth herein.

42. Paragraph 42 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly further denies it had a duty to warn consumers directly of alleged risks associated with the use of Cymbalta®.

43. Paragraph 43 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 43.

44. Paragraph 44 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 44.

45. Lilly denies the allegations in Paragraph 45. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 45 relating to Plaintiff's alleged injuries and therefore denies the same.

46. Paragraph 46 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 46 relating to Plaintiff's alleged injuries and therefore denies the same.

47. Lilly denies the allegations in Paragraph 47, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 47. Lilly denies that Plaintiff is entitled to any such relief.

**COUNT II - STRICT PRODUCTS LIABILITY - DESIGN DEFECT**

48. Lilly reincorporates and realleges its Responses to Paragraphs 1-47 of Plaintiff's Complaint as if fully set forth herein.

49. Lilly admits that it has sold Cymbalta® in New York. Paragraph 49 is vague and ambiguous as to time and on that basis, Lilly denies the remaining allegations.

50. The allegations in Paragraph 50 are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations.

51. Lilly denies the allegations in Paragraph 51.

52. Lilly denies the allegations in Paragraph 52.

53. Lilly denies the allegations in Paragraph 53.

54. Lilly denies the allegations in Paragraph 54.

55. Lilly denies the allegations in Paragraph 55.

56. Paragraph 56 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, the allegations in Paragraph 56 are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations.

57. Lilly denies the allegations in Paragraph 57.

58. Lilly admits that it researched, tested, developed, manufactured, labeled, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the



medication. The remaining allegations pertaining to Lilly's "product" are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations and legal conclusions in Paragraph 58 relating to Plaintiff's alleged injuries from Cymbalta® and therefore denies the same. Lilly denies the remaining factual allegations in Paragraph 58.

59. Lilly admits that it researched, tested, developed, manufactured, labeled, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 59 and therefore denies the same.

60. Lilly denies the allegations in Paragraph 60.

61. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 61 relating to Plaintiff's alleged use of Cymbalta® and therefore denies the same.

62. Paragraph 62 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

63. Paragraph 63 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 63 relating to Plaintiff's alleged injuries and therefore denies the same.

64. Lilly denies the allegations in Paragraph 64, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 64. Lilly denies that Plaintiff are entitled to any such relief.

**COUNT III - STRICT PRODUCTS LIABILITY - FAILURE TO WARN**

65. Lilly reincorporates and realleges its Responses to Paragraphs 1-64 of Plaintiff's Complaint as if fully set forth herein.

66. Lilly admits that it researched, tested, developed, manufactured, labeled, distributed, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly further admits that it has utilized direct-to-consumer advertising for Cymbalta®, in conformity with applicable rules and regulations. Lilly objects to the term "persons responsible for consumers" as vague and ambiguous and on that basis denies the allegation. Paragraph 66 further purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 66.

67. Paragraph 67 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

68. Plaintiff's allegation pertaining to "exclusive control" is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegation. Lilly denies the remaining allegations in Paragraph 68.

69. Lilly denies the allegations in Paragraph 69.

70. Paragraph 70 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 70.

71. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 71 relating to Plaintiff's alleged use of Cymbalta® and therefore denies the same.

72. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations relating to Plaintiff or Plaintiff's physician's ability to discover any alleged "defect in the drug" and therefore denies the same. Lilly denies any remaining allegations in Paragraph 72.

73. Lilly admits that it is engaged in the business of researching, developing, testing, manufacturing, promoting, distributing, marketing, and selling prescription medications, including but not limited to Cymbalta®. Paragraph 73 purports to allege conclusions of law that do not require a response and on that basis, Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 73.

74. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 74 relating to Plaintiff's or Plaintiff's physician's knowledge and therefore denies the same. Lilly denies the remaining allegations in Paragraph 74.

75. Paragraph 75 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 75.

76. Lilly denies the allegations in Paragraph 76.

77. Lilly denies the allegations in Paragraph 77.

78. Lilly denies the allegations in Paragraph 78.

79. Paragraph 79 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 79 relating to Plaintiff's alleged injuries and therefore denies the same.

80. Lilly denies the allegations in Paragraph 80, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 80. Lilly denies that Plaintiff is entitled to any such relief.

#### **COUNT IV - BREACH OF IMPLIED WARRANTY**

81. Lilly reincorporates and realleges its Responses to Paragraphs 1-80 of Plaintiff's Complaint as if fully set forth herein.

82. Paragraph 82 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 82 relating to Plaintiff's alleged injuries and therefore denies the same.

83. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 83 and therefore denies the same.

84. Lilly admits that it researched, tested, developed, manufactured, labeled, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 84 and therefore denies the same.

85. Lilly denies the allegations in Paragraph 85.

86. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 86.

87. Paragraph 87 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 87 relating to Plaintiff's alleged injuries and therefore denies the same.

88. Paragraph 88 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations.

89. Paragraph 89 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 89 relating to Plaintiff's injuries and therefore denies the same.

90. Paragraph 90 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 90 relating to Plaintiff's alleged injuries and therefore denies the same.

91. Lilly denies the allegations in Paragraph 91, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 91. Lilly denies that Plaintiff is entitled to any such relief.

#### **COUNT V - NEGLIGENT MISREPRESENTATION**

92. Lilly reincorporates and realleges its Responses to Paragraphs 1-91 of Plaintiff's Complaint as if fully set forth herein.

93. Paragraph 93 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly further denies it had a duty to warn consumers directly of alleged risks associated with the use of Cymbalta®.

94. Lilly denies the allegations in Paragraph 94.

95. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 95 relating to what Plaintiff or Plaintiff's physician saw. Lilly denies the remaining allegations in Paragraph 95.

96. Paragraph 96 purports to allege a conclusion of law that does not require a response and on that basis Lilly denies the allegations. Lilly further denies the remaining allegations in Paragraph 96.

97. Lilly denies the allegations in Paragraph 97.

98. Lilly denies the allegations in Paragraph 98. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 98 and therefore denies the same.

99. Paragraph 99 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 99 and therefore denies the same.

100. Lilly denies the allegations in Paragraph 100. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 100 relating to Plaintiff or Plaintiff's physician's actions and therefore denies the same.

101. Paragraph 101 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 101 and therefore denies the same.

102. Paragraph 102 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 102 relating to Plaintiff's alleged injuries and therefore denies the same.

103. Lilly denies the allegations in Paragraph 103, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 103. Lilly denies that Plaintiff is entitled to any such relief.

#### **COUNT VI—FRAUD**

104. Lilly reincorporates and realleges its Responses to Paragraphs 1-103 of Plaintiff's Complaint as if fully set forth herein.

105. Lilly denies the factual allegations in Paragraph 105. To the extent that Paragraph 105 purports to allege conclusions of law that do not require a response, Lily further denies those allegations.

106. Lilly denies the factual allegations in Paragraph 106. To the extent that Paragraph 105 purports to allege conclusions of law that do not require a response, Lily further denies those allegations.

107. Lilly denies the factual allegations in Paragraph 107. To the extent that Paragraph 107 purports to allege conclusions of law that do not require a response, Lily further denies those allegations.

108. Lilly denies the factual allegations in Paragraph 108. To the extent that Paragraph 108 purports to allege conclusions of law that do not require a response, Lily further denies those allegations.

109. Lilly denies the allegations made in Paragraph 109. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 109 and therefore denies the same.

110. Paragraph 110 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 110 and therefore denies the same.

111. Paragraph 111 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 111 and therefore denies the same.

112. Paragraph 112 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 112 and therefore denies the same.

113. Paragraph 113 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 113 relating to Plaintiff's alleged injuries and therefore denies the same.



114. Lilly denies the allegations in Paragraph 114, except that Lilly admits only that Plaintiff seek the relief set forth in Paragraph 114. Lilly denies that Plaintiff is entitled to any such relief.

**COUNT VII - VIOLATION OF CONSUMER PROTECTION LAWS**

115. Lilly reincorporates and realleges its Responses to Paragraphs 1-114 of Plaintiff's Complaint as if fully set forth herein.

116. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 116 and therefore denies the same.

117. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 117 and therefore denies the same.

118. Paragraph 118 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

119. Lilly denies the factual allegations in Paragraph 119. To the extent that Paragraph 119 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

120. Lilly denies the factual allegations in Paragraph 120. To the extent that Paragraph 120 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

121. Lilly denies the factual allegations in Paragraph 121. To the extent that Paragraph 121 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

122. Lilly denies the factual allegations in Paragraph 122. To the extent that Paragraph 122 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

123. Lilly denies the factual allegations in Paragraph 123. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 123 relating to Plaintiff or Plaintiff's physician's ignorance and therefore denies the same. To the extent that Paragraph 123 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

124. Lilly denies the factual allegations in Paragraph 124. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 124 relating to Plaintiff or Plaintiff's physician's actions and therefore denies the same. To the extent that Paragraph 124 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

125. Lilly denies the factual allegations in Paragraph 125. To the extent that Paragraph 125 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

126. Lilly denies the factual allegations in Paragraph 126. To the extent that Paragraph 126 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

127. Paragraph 127 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

128. Lilly denies the factual allegations in Paragraph 128. To the extent that Paragraph 128 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

129. Lilly denies the factual allegations in Paragraph 129. To the extent that Paragraph 129 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

130. Lilly denies the allegations in Paragraph 130, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 130. Lilly denies that Plaintiffs are entitled to any such relief.

#### **PLAINTIFF'S PRAYER FOR RELIEF**

Lilly denies the allegations in this section of Plaintiff's Complaint, except that Lilly admits only that Plaintiff seeks the relief set forth in this section. Lilly denies that Plaintiff is entitled to any relief whatsoever.

#### **AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Lilly in this matter. Lilly, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Lilly may withdraw any of these affirmative defenses as may be appropriate. Further, Lilly reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Lilly states the following:

#### **FIRST AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

#### **SECOND AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

### **THIRD AFFIRMATIVE DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

### **FOURTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening or superseding cause or causes.

### **FIFTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based upon an alleged failure by Lilly to warn Plaintiff directly of alleged dangers associated with the use of Cymbalta®, such claims are barred under the learned intermediary doctrine because Lilly has discharged its duty to warn in its warnings to the prescribing physician.

### **SIXTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff asserts claims based on Lilly's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

### **SEVENTH AFFIRMATIVE DEFENSE**

If the Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

### **EIGHTH AFFIRMATIVE DEFENSE**

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by application of the doctrine of comparative fault.

**NINTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Lilly or other manufacturer.

**TENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Lilly and over whom Lilly had not control and for whom Lilly may not be held accountable.

**ELEVENTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Cymbalta®.

**TWELFTH AFFIRMATIVE DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural course of conditions for which this Defendant is not responsible.

**THIRTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Lilly reserves the right to assert a nonparty defense under New York law.

#### **FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

#### **SIXTEENTH AFFIRMATIVE DEFENSE**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted violate Lilly's state and federal rights.

#### **SEVENTEENTH AFFIRMATIVE DEFENSE**

No act or omission of Lilly was willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

#### **EIGHTEENTH AFFIRMATIVE DEFENSE**

Plaintiff has not suffered any actual injury or damages.

#### **NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are bared in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

#### **TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Lilly provided legally adequate "directions or warnings" as to the use of Cymbalta® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement of (Second) of Torts.

#### **TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

#### **TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

#### **TWENTY-THIRD AFFIRMATIVE DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Cymbalta®.

#### **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

#### **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred in whole or in part because Lilly's conduct conforms with medical knowledge.

#### **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

#### **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

All activities of Lilly as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

#### **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Lilly denies, then it was unavoidably unsafe as defined

in the Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

#### **TWENTY-NINTH AFFIRMATIVE DEFENSE**

Lilly's advertisement and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and New York Constitutions.

#### **THIRTIETH AFFIRMATIVE DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

#### **THIRTY-FIRST AFFIRMATIVE DEFENSE**

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Lilly in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

#### **THIRTY-SECOND AFFIRMATIVE DEFENSE**

With respect to each and every purported cause of action, the acts of Lilly were at all times done in good faith and without malice.

#### **THIRTY-THIRD AFFIRMATIVE DEFENSE**



To the extent there were any risks associated with the use of the product which is the subject matter of this action which Lilly knew or should have known and which gave rise to a duty to warn, Lilly at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

#### **THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims against Lilly are barred because Plaintiff's treating physicians fully informed Plaintiff of the risks associated with the use of Cymbalta. Any informed consent and/or release given by Plaintiff is pleaded as an affirmative defense.

#### **THIRTY-FIFTH AFFIRMATIVE DEFENSE**

To the extent Plaintiff's claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2000).

#### **THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiff has not sustained an ascertainable loss of property or money.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Lilly to determine all of its legal, contractual, and equitable rights, Lily reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Lilly will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Lilly respectfully demands judgment dismissing the Complaint with prejudice and awarding Lilly its reasonable costs and disbursements, including reasonable

attorneys' fees, together with such and other and further relief that the court may deem just and proper.

**JURY DEMAND**

Lilly demands a trial by jury as to all issues triable.

Dated: New York, New York  
August 30, 2013

COVINGTON & BURLING LLP

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